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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,766	12/12/2003	David Chien	PP-20001.002	9349

27476 7590 11/21/2008

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EXAMINER	
POHNERT, STEVEN C	

ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
11/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/733,766	CHIEN ET AL.	
	Examiner	Art Unit	
	Steven C. Pohnert	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,14-18 and 20-34* is/are pending in the application.

4a) Of the above claim(s) *20-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,14-18 and 32-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

This action is in response to the papers filed on 8/5/2008.

Claims 2-3, 6-13, and 19 are canceled.

Claims 1, 4-5, 14-18, 20-34 are pending.

Claims 20-31 are withdrawn from consideration as drawn to a non-elected invention.

Claims 1, 4-5, 14-18 and 32-34 are under examination.

The 103 rejections based on the combination of Husain and Muir has been with drawn in view of the amendments.

Any rejection not reiterated below has been withdrawn.

This action is FINAL.

Claim Rejections - 35 USC § 103-New Grounds

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 4-5, 14, 17-18 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bellamy et al (US Patent 2,896,619, issued July 28, 1959) in

view of Husain (US Patent 4,708,850 issue Nov 24, 1987) and Muir et al, (WO 1999/26724, published June 3, 1999).

This is a new a maintained rejection that has been modified in view of the instant amendments.

It is noted that claim 18 requires either the catalytic molecule and reporter sequence is lyophilized, not both.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, the structure meets the claim limitations.

Bellamy teaches an apparatus for blood collecting and storage and sampling for testing (column 1, lines 15-20). Bellamy teaches when the blood storage device is full it is sealed off by tying of a knot (column 3, lines 15-20). Bellamy further teaches samples of blood can be sealed by clamps and dieletrically heat sealed (column 3, lines 53-56). Bellamy teaches the blood products are stored for two to three days (column 4, lines 15-17). Bellamy thus teaches a closed biological storage device for storing blood samples several days and permanent sealing of samples from the container.

However, Bellamy does not teach a blood container having a plurality of outlets with an open seal between the container and each outlet that can be permanently sealed, at least a first section for holding a portion of the blood or blood product and closed seal between a first and second section in which a second section comprises a lyses buffer and an isotonic solution and a closed seal between a second and third

section where the third section has a test reagent (claim 1). Bellamy et al does not teach a device with a plurality of outlets which comprise three sections, including a lyses buffer and two reagents, wherein in one of the two reagents is either lyophilized or bound to a solid support (claim 1 and 18). Bellamy does not teach a closed container or a seal between each outlet and Husain does not teach a catalytic molecule and report sequence (claim 18). Bellamy et al does not teach the device comprises blood platelets.

However, Hussain teaches a blood storage and testing device with outlets protruding from the side (see figure 3 and abstract). Husain teaches a container (10) for receiving and storing blood. Husain teaches there are at least 3 outlets protruding from the side (see column 5, line 39). Husain teaches each protruding outlet may be suitably closed (see column 5, lines 52-53). Husain teaches the samples in container 10 are separated from the reagents in outlets protruding form the container (10) by fracturable seals (see figure 6 and 7). Hussain teaches his blood storage device reduces the number of test tubes and samples that need to be individually handled.

Further, Muir teaches a device and method for detecting target molecules in a biological sample (see abstract). Muir teaches "a test device comprises a receptacle this is attached to at least one sample collection unit housing biological fluid" (see page 3, lines 17-22). Muir teaches, "one compartment comprises at least one cell lysing reagent, another compartment comprises at least one reagent for the inactivation of amplification inhibitors, another compartment comprises at least one reagent for nucleic acid amplification and another compartment comprises at least one reagent for labeling

at least one target molecule, wherein the labeled target molecule is subject to a method of detection" (see page 4, lines 21-29). Muir teaches one reagent is affixed to the biocompatible material of the compartment (see page 11, lines 4-7). Muir thus teaches one reagent is bound to a solid support. Muir further teaches, "one target polynucleotide on a solid support"(see page 18, lines 5-6). Muir teaches the use of lyophilized components (see page 56, line 26). Muir teaches the sealing of compartments by thermal or ultrasonic welding (see page 57, lines 24-26). Muir teaches his device advantageously allows the sample and potentially biohazardous materially to be sealed within the device (see page 58, lines 10-13). Muir further teaches his device allows for extended storage and increased shelf life (see page 61, line 10-13).

Muir teaches the receptacle can be completely sequestered from the reaction chamber (see page 10, lines 9-11). Muir teaches this sequestering can be via a valve (see page 12, lines 28-30).

Muir teaches the invention contains breakable partitions that allow mixing of contents from 2 adjacent compartments (see page 3, lines 26-29; page 12, lines 4-11).

Muir teaches the use of PCR amplification to detect a polynucleotide sequence (see page 16, lines 22-23). The polymerase used in PCR is a catalytic enzyme and the primers used for PCR are interpreted as a reporter sequence.

With regards to claim 33 and 34, Muir teaches bodily fluids include blood (see page 3 line 8), which comprise platelets. Muir further teaches assays to determine

bacterial growth in platelets (page 75, lines 25-26) using probes to 16S rRNA (see page 76 lines 7-8).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention to improve the apparatus of Bellamy by incorporation Husain's protruding outlets and multiple assay device with Muir's multicompartment blood testing device with lyses buffer in one section, and at least a test reagents of which one is either lyophilized or bound to a solid support in another section. The skilled artisan would be motivated to combine the teachings of Bellamy, Husain and Muir because Husain teaches his multiple analysis system does not require as much handling and labeling and Muir teaches compartmentation of the reagents allows for longer shelf live and storage. The combination of Bellamy, Husain and Muir would result in a closed container for receiving and storing blood for several days, with a plurality of outlets with an open seal situated between the container and outlet so the sample in the outlet can be sealed off and analyzed by reagents that are in the second and third section of the outlet that are separated by a breakable seal. The artisan would have reasonable expectation of success of combining the blood storage apparatus of Bellamy with the protruding outlet structure of Husain and the reagents of Muir as they are all drawn to containers for storage and analysis of biological samples.

Response to Arguments

The response asserts that the previously presented rejection did not render the instant claims obvious as it did not teach a closed container or sealable outlets. The examiner has presented the teachings of Bellamy to address the asserted deficiencies

and render the pending claims obvious, as Bellamy teaches a closed container and sealing of samples. Thus the instant rejection has been presented.

3. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bellamy et al (US Patent 2,896,619, issued July 28, 1959), Husain (US Patent 4,708,850 issue Nov 24, 1987) and Muir et al, (WO 1999/26724, published June 3, 1999) as applied to 1, 4-5, 14, 17-18 and 32-34 above, and further in view of Shih et al (US Patent 5589332 December 1996).

This rejection is new grounds of rejection necessitated by amendment.

The teachings of Bellamy, Husain and Muir are set forth above in paragraph 2.

Bellamy, Hussain and Muir do not teach a ribozyme or RNA reporter (claim 18) or immobilization of a ribozyme or RNA reporter on a solid support (claim 17).

However, Shih teaches an activated ribozyme complex which includes the ribozyme, co-target molecule (RNA) and disease target molecule (see column 5, lines 1-3) for the diagnostic detection of clinical samples (see column 5 line 65) pathogenic agents, which include viruses, bacteria, or fungi (see column 8 lines 53-54). Shih further teaches use of ribozymes in diagnostics provides high specificity and simple, sensitive and quantitative assays (see column 4 lines 44-46). As Shih teaches, "The methodology for the construction of a regulatable ribozyme, in which a ribozyme sequence is linked to a ligand-binding sequence, placing the activity of the ribozyme under the control of that ligand and requiring its presence for activation or inactivation is described below" (see column 8, lines 64- top of column 9). Shih further teaches the co-target is a RNA molecule that can be

anchored to a solid support (see column 5 lines 11-14) to allow quantification (see column 3, lines33-34).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to include the diagnostic ribozymes and RNA co-targets of Shih in the blood storage and testing device of Bellamy, Husain and Muir because both Muir and Shih teach testing of blood for pathogens. Shih further teaches ribozymes provide a highly specific simple quantifiable method for detecting virus, fungi, or bacteria in clinical samples. One of ordinary skill in the art would be motivated to improve the blood-testing device of Bellamy, Husain and Muir with the diagnostic ribozymes and co-targeting RNA of Shih because the diagnostic ribozymes and co-targets allow a simple sensitive and quantifiable assay of pathogens in clinical samples. The ordinary artisan at the time the invention was made would be further motivated to combine the blood testing device of Bellamy, Husain, and Muir with the covalently attached co-target of Shih, because it would improve quantitation of clinical sample pathogen assays. The ordinary artisan would be motivated to covalently attach the co-target, because Shih teaches it would allow quanititation. The skilled artisan would have a reasonable expectation of success as Muir and Shih are all drawn to methods of detecting nucleic acids by hybridization and Bellamy and Husain teach a sample storage device with separate compartments for analysis of samples.

Response to Arguments

The response asserts that Shih does not overcome the deficiencies of the previously presented rejection based on Husain and Muir. The rejection of Husain and

Muir has been withdrawn in light of the amendments and new rejection based on Bellamy, Husain and Muir has been presented.

Summary

No claims are allowed over prior art cited.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven C. Pohnert whose telephone number is (571)272-3803. The examiner can normally be reached on Monday-Friday 6:30-4:00, every second Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Steven Pohnert

/Sarae Bausch/
Primary Examiner, Art Unit 1634